COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22-XI-2007
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NOT FOR PUBLICATION

COMMISSION DECISION

of 22-XI-2007

amending the marketing authorisation for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use, granted by Decision C(2004)3160

(ONLY THE DUTCH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 22-XI-2007

amending the marketing authorisation for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use, granted by Decision C(2004)3160

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application(s) submitted by Eli Lilly Nederland B.V. on 22 July 2007 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 18 October 2007,

Whereas:

(1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "Ariclaim - duloxetine hydrochloride", which is entered in the Community Register of Medicinal Products under number(s) EU/1/04/283/001-007 and the placing on the market of which was authorised by Decision C(2004)3160 of 11 August 2004, has shown that the product remains in compliance with the requirements set out in Directive

[1] OJ L 136, 30.4.2004, p. 1, Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).
[2] OJ L 159, 27.6.2003, p. 24.

2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2004)3160 accordingly.

(3) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2004)3160 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3160 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Eli Lilly Nederland B.V., Grootslag 1-5, 3991 RA Houten, Nederland.

Done at Brussels, 22-XI-2007

For the Commission
Heinz ZOUREK
Director-General

[3] OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).